SUPREME COURT, U.S.
FILED
MAY 9 2003
OFFICE OF THE CLERK

No. 02-1251

IN THE

Supreme Court of the United States

EVELYN HEINRICH and HENRY M. SIENKEWICZ, JR.,

Petitioners,

v.

ELIZABETH DUTTON SWEET and FREDERICK H. GREIN, JR., Representatives of the Estate of WILLIAM H. SWEET, M.D., and MASSACHUSETTS GENERAL HOSPITAL,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF IN OPPOSITION FOR RESPONDENT MASSACHUSETTS GENERAL HOSPITAL

JOSEPH L. DOHERTY, JR.
Counsel of Record
JOSEPH L. DOHERTY, JR.
AND ASSOCIATES
Attorneys for Respondent
Massachusetts General Hospital
225 Franklin Street
26th Floor
Boston, MA 02110
(617) 217-2837

180743

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED FOR REVIEW

I. Whether this Court should deny the Plaintiffs' Petition for Writ of Certiorari, pursuant to S. Ct. R. 10, based upon the fact that the decision of the Court of Appeals properly stated and applied the appropriate rules of law and standards of appellate review to the issues presented by the Petitioners' and Respondents' cross-appeals from the Judgments entered by the District Court in these actions.

II. Whether the Court of Appeals properly vacated the jury verdicts against the Respondents, Massachusetts General Hospital and William H. Sweet, M.D., and ordered the entry of Judgment in their favor, based upon its determination that the evidence presented at trial was wholly inadequate and insufficient, as a matter of law, to support or uphold the original jury verdicts in favor of the Petitioners.

TABLE OF CONTENTS

Page

Question Presented for Review i

Table of Contents ii

Table of Cited Authorities iv

Statement of the Case 1

Reasons for Denying the Writ 8

A. The Plaintiffs' Petition does not present issues that warrant review by this Court, because the decision of the Court of Appeals properly stated and applied the appropriate rules of Massachusetts law and the correct standards of appellate review to the issues presented by the Petitioners' and Respondents' cross-appeals. 8

B. The Court of Appeals properly vacated the jury verdicts against the Respondents, Massachusetts General Hospital and William H. Sweet, M.D., and ordered the entry of Judgment in their favor, based upon its determination that the evidence presented at trial was wholly inadequate and insufficient, as a matter of law, to support or uphold the original jury verdicts in favor of the Petitioners. 14

1. The Negligence Claims 14

2. The Wrongful Death Claims 17

Contents

Page

C. The Plaintiffs' Petition contains numerous misstatements of the evidence 20

Conclusion 22

TABLE OF CITED AUTHORITIES

Page

Cases:

Boag v. MacDougall, 454 U.S. 364 (1982) 8, 9, 25

Broderick v. Gibbs, 1 Mass. App. Ct. 822, 296 N.E.2d 708 (1973) 15

Brune v. Belinkoff, 354 Mass. 102, 235 N.E.2d 793 (1968) 6, 14, 15

Civatarese v. Gorney, 358 Mass. 652, 266 N.E.2d 668 (1971) 18

Corriveau v. United States, 832 F. Supp. 19 (D. Mass. 1993) 18

Edwards v. Warwick, 317 Mass. 573, 59 N.E.2d 194 (1945) 6, 17, 18, 19

Forlano v. Hughes, 471 N.E.2d 1315 (Mass. 1984) 14, 15

Heinrich v. Sweet, 308 F.3d 48 (1st Cir. 2002) 10

Layne & Bowler Corp. v. Western Well Works, Inc., 261 U.S. 387 (1923) 9

Reeves v. Sanderson Plumbing Products, Inc., 530 U.S. 133 (2000) 12

Cited Authorities

	Page
Rogers v. Okin, 478 F. Supp. 1342 (1979)	14
Stepakoff v. Kantar, 393 Mass. 836, 473 N.E.2d 1131 (1985)	14
Walker v. Gage, 223 Mass. 179, 111 N.E. 766 (1916)	18
Walton v. Nalco Chemical Co., 272 F.3d 13 (1st Cir. 2001)	11
Rule:	
S. Ct. R. 10	i, 8, 25

STATEMENT OF THE CASE

This is an action arising out of medical care and treatment provided by the Respondents, Dr. William Sweet and Massachusetts General Hospital, ("MGH"), to the Petitioners' decedents, Eileen Sienkewicz and George Heinrich, more than forty years ago. At the time of their treatment, both Mrs. Sienkewicz and Mr. Heinrich were suffering from a condition known as glioblastoma multiforme, the deadliest form of brain cancer in humans. (JA 4153). Untreated, or even when treated with craniotomy, (surgical removal of tumor from the brain), or conventional radiation, glioblastoma multiforme was invariably fatal, with typical survival times of six to eight months from the date of diagnosis. (JA 4153). It was an incurable disease in 1960, when Mrs. Sienkewicz and Mr. Heinrich were first diagnosed, and it remains an incurable disease today. (JA 2376).

In the early 1950's, Dr. William H. Sweet, the late Chief of Neurosurgery at Massachusetts General Hospital, and other researchers, began working to develop a potential cure for glioblastoma multiforme, through a new method of radiation treatment known as boron neutron capture therapy ("BNCT"). (JA 2962). The theory of BNCT arose out of scientific research relating to nuclear physics and atomic energy conducted in the 1930's. (JA 1063). Physicists had learned that when a boron atom, (number 5 on the table of elements with 5 protons), is subjected to neutron radiation, the boron atom will "split" into two smaller atoms, helium, (number 2 on the table of elements with 2 protons), and lithium, (number 3 on the table of elements with 3 protons), giving off a tiny burst of nuclear energy. (JA 1061-1063).

Dr. Sweet and other medical researchers recognized that if a significant concentration of boron atoms could be introduced into tumor tissue within the brain, and that tumor tissue was then exposed to a beam of neutron radiation, the resulting multiple small bursts of nuclear energy would kill the surrounding tumor cells. (JA 2828-2829). Unlike conventional forms of radiation therapy, slow neutron radiation is low in energy and does not, in and of itself, cause any significant risk of harm to human tissue. (JA 2956-2961). However, when neutron radiation is focused upon tumor tissue containing boron atoms, the neutrons are "captured" by the boron atoms, (causing the split into helium and lithium atoms described previously), and a significant concentration of localized radiation is delivered directly to the tumor tissue. (JA 2828-2833). Dr. Sweet was one of the primary researchers involved in the first clinical trials of BNCT, conducted at the Brookhaven National Laboratories, in New York, in 1950 and 1951. (JA). He continued working to develop and improve BNCT throughout the 1950's, primarily at Brookhaven. (JA 2962-2971).

In 1959 Dr. Sweet began assembling a team of doctors, physicists and chemists to prepare for further clinical trials of BNCT in Massachusetts. The treatment would be provided in a specially designed operating room beneath a new nuclear reactor at the Massachusetts Institute of Technology, (MIT), in Cambridge, Massachusetts. (JA 2971-2980). The reactor was built under the auspices of the United States Atomic Energy Commission and became operational in 1958. (JA 4023-24). Mrs. Sienkewicz and Mr. Heinrich had been diagnosed with glioblastoma multiforme in 1960. They were provided an opportunity to participate in the program and receive BNCT at the MIT facility. In view of the fatal nature of their disease, and with no other effective treatment options available to them, Mrs. Sienkewicz and Mr. Heinrich agreed to participate in the

clinical trials, in the hope that BNCT could potentially cure their disease, or at least prolong their lives.[1] (JA 1222-1230).

Prior to the start of the clinical trials at MIT, Dr. Sweet's team conducted extensive animal studies and evaluated more than 145 potential boron compounds to determine the best compounds to be used when the trials began upon patients. (JA 1851, 2231-45, 2270-73, 2336-39). Dr. Sweet's team also built upon extensive research conducted by others, including quantitative studies of the effects of ionizing radiation on monkeys, rabbits, and mice and of the destruction of animal tumors using BNCT. (JA 3901-02).

On November 13, 1960, Mrs. Sienkewicz became the first patient to receive BNCT in the clinical trials at MIT. (JA 2866, 2977). Almost four months later, on March 4, 1961, x-ray studies showed that she had "no definite diagnosis of recurrent tumor." (JA 6372). However, in August of 1961 she was found to have recurrence of her tumor. (JA 6365). Mrs. Sienkewicz was admitted to MGH in September 1961. She died on October 31, 1961, almost seventeen months after her initial diagnosis of glioblastoma multiforme and almost one year after undergoing BNCT. (JA 6365-66).

George Heinrich was the sixth patient to receive BNCT during the clinical trials at MIT. (JA 2882). He had been diagnosed with a glioblastoma multiforme in October, 1960. (JA 6082, 6305). Attempts at surgical removal of the tumor and conventional radiation were ineffective, with the tumor

---

1. Although the plaintiffs claimed that Mrs. Sienkewicz and Mr. Heinrich were not fully informed of the risks attendant to the treatment, the jury found in favor of Dr. Sweet and MGH on the plaintiffs' claims alleging lack of informed consent. (JA 177-179).

growing back after only a few weeks. (JA 6097, 6123). Mr. Heinrich received BNCT at the MIT facility on January 18, 1961, approximately two months after Mrs. Sienkewicz had received her treatment. (JA 2882). (As of that time, Mrs. Sienkewicz appeared to be doing well, with no evidence of recurrence of her tumor). (JA 6372). Unfortunately, BNCT did not appear to have any significant beneficial effect upon Mr. Heinrich's tumor. In April, 1961, a brain scan showed apparent recurrence of the tumor. He died on May 27, 1961. (JA 6307).

A total of sixteen patients received BNCT between November, 1960, and August, 1961, at the MIT reactor. Despite initial optimism, based upon the results first experienced by Mrs. Sienkewicz, all of the patients eventually died. (JA 3915). Autopsy findings and subsequent research eventually demonstrated that although the BNCT had been effective in destroying tumor tissue, it also caused unanticipated damage to adjacent blood vessels, apparently due to a sequestering of the boron compound within the walls of the vessels, resulting in selectively high doses of radiation to those vessels. (JA 2850). This complication was not known (and, logically, could not have been known), until after the conclusion of the clinical trials and the review and analysis of the autopsy results of the sixteen patients. (JA 1903-04, 2282-83, 2286-88, 2349). The results of the autopsy studies were first presented at a conference in 1964. They were first published in 1972, in what has become known as the Asbury Article, written by a Dr. Arthur Asbury, along with Dr. Sweet, and introduced as Exhibit 1 at the trial of this case in the District Court. (JA 0844, 2832-38, 2851-52).

Thirty four years after Mrs. Sienkewicz and Mr. Heinrich died, attorneys representing their estates filed a class action

in the United States District Court for the Eastern District of New York. In the eleven-count Complaint they asserted claims for alleged violations of constitutional and civil rights under the *Bivens* doctrine, civil fraud, battery, intentional infliction of emotional distress, strict liability for inherently dangerous activities, personal injury caused by exposure to toxic substances, lack of informed consent, wrongful death, "civil responsibility for crimes against humanity," negligence, and negligent misrepresentation. On August 20, 1997, Judge Hurley of the Eastern District of New York ordered the case transferred to the District of Massachusetts, where it was initially assigned to Judge Wolf on September 25, 1997. (JA 5).

Thereafter, the defendants filed various motions to dismiss the actions. The motions were scheduled for hearing on March 18, 1999, before Judge Wolf. (JA 11). However, on March 1, 1999, the case was reassigned to Chief Judge William Young. (JA 11). Judge Young ordered that the case would proceed to trial in six months, despite the fact that no discovery had been conducted by any of the parties, due to an agreement by the parties to stay discovery until after the court decided the motions to dismiss. (JA 11).

Trial was scheduled to begin on September 10, 1999. Based upon various rulings and decisions of the District Court prior to trial, the plaintiffs' only remaining causes of action, as of September 1, 1999, were their *Bivens* claims, under federal law, and their Massachusetts state law claims for negligence, wrongful death and lack of informed consent. On September 9, 1999, one day prior to opening statements, the Court heard argument upon the defendants' motions for Judgment as a Matter of Law, (JA 396-460), and allowed those motions as to all of the plaintiffs' federal Civil Rights claims under *Bivens*. (JA 460). Consequently, the only matters

presented to the jury at trial were state law claims under Massachusetts law.

The jury heard evidence over fourteen days, between September 10 and October 7, 1999. During trial, the plaintiffs called two expert witnesses to provide testimony in support of their claims. Dr. Larry Junck, a neurologist and neuro-oncologist, was their only medical expert. (The plaintiffs' second expert, Dr. Michael Grodin, described himself as a medical ethicist). The only testimony provided by Dr. Junck as to the plaintiffs' claims of negligence, wrongful death and lack of informed consent was his personal opinion that the decision to proceed with BNCT, without knowledge of all the potential risks was "irresponsible" and "inappropriate." (JA 985:11-987:21) (see also JA 988:25-989:13). Dr. Junck was never asked to provide an expert opinion specifically directed to the question of whether the defendants deviated from the applicable standards of care in 1960. (JA 1116, 1129). Such expert testimony is required under Massachusetts law, in order for a plaintiff to establish claims of medical negligence and/or wrongful death and in order for the Court to submit those claims to the jury for consideration. *Brune v. Belinkoff*, 354 Mass. 102, 109, 235 N.E.2d 793, 798 (1968). In addition, Dr. Junck admitted during cross examination, that it was impossible for him to say whether BNCT *hastened* the deaths of either Mrs. Sienkewicz or Mr. Heinrich in any way. (JA 945-946, 952-954, JA 1116 and 1129). Under Massachusetts law, in order to recover damages in an action alleging wrongful death, a plaintiff must prove that the alleged negligence hastened the death of the plaintiff's decedent. *Edwards v. Warwick*, 317 Mass. 573, 577-578, 59 N.E.2d 194, 196 (1945)

Dr. Grodin 's testimony related primarily to the plaintiffs' claims for lack of informed consent. The jury ultimately found in favor of Dr. Sweet and MGH on those claims. (JA 177-79). Neither Dr. Junck nor Dr. Grodin ever provided any testimony that Dr. Sweet violated any standards of care of the average qualified neurosurgeon practicing in 1960 or 1961.[2] (JA 924-1196).

During trial, Judge Young determined, over the defendants' objection, that he would instruct the jury under the 1995 version of the Massachusetts wrongful death statute, rather than the version of the statute in effect at the time of the treatment and the deaths in 1960 and 1961. (Pet. App. 37a-72a). On October 15, 1999, the jury found in favor of the defendants as to the plaintiffs' claims alleging lack of informed consent, but found in favor of the plaintiffs, on the negligence/wrongful death claims, awarding compensatory damages of $3,000,000 and punitive damages of $5,000,000. (JA 177-179). Dr. Sweet and MGH filed timely motions for judgment as a matter of law and/or for a new trial.

On September 29, 2000, Judge Young issued a written opinion, reversing his earlier decision than the 1995 version the Massachusetts wrongful death statute applied to this action, ruling that the 1960-61 version of the statute applied. (Pet. App. 37a-72a). This decision reduced the compensatory and punitive damage awards for wrongful death to $20,000, (reducing the overall award of damages from $8,000,000 to approximately $800,000). The Court otherwise denied the post-trial motions, without issuing a written opinion or providing any specific rulings from the bench setting forth

2. The Plaintiffs only direct claims of negligence and wrongful death were against Dr. Sweet. The claims against MGH were for vicarious liability based upon the alleged liability of Dr. Sweet.

its reasons for its denial of the motions. The parties filed timely cross appeals from the jury verdicts, from the Trial Court's rulings and from the Judgments.

In an opinion issued on August 27, 2002, the Court of Appeals for the First Circuit vacated the Judgments in their entirety, ruling that Judgment should have been entered for Dr. Sweet and MGH as a matter of law, because plaintiffs had failed to present legally sufficient evidence to support their negligence and wrongful death claims:

REASONS FOR DENYING THE WRIT

A. The Plaintiffs' Petition does not present issues that warrant review by this Court, because the decision of the Court of Appeals properly stated and applied the appropriate rules of Massachusetts law and the correct standards of appellate review to the issues presented by the Petitioners' and Respondents' cross-appeals.

Rule 10 of this Court states that "[a] petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." That language was added by an amendment to the Rule in 1995, acknowledging the well recognized principle that "[t]he Supreme Court is not, and never has been, primarily concerned with the correction of errors in lower court decisions." *Boag v. MacDougall*, 454 U.S. 364, 368 (1982) (Rehnquist, J., dissenting) (*quoting* Address of Chief Justice Vinson before the American Bar Association, Sept. 7, 1949). The Court's function is "to resolve conflicts of opinion on federal questions that have arisen among lower courts, to pass upon questions of wide import under the Constitution, laws, and treaties of the United

States, and to exercise supervisory power over the lower federal courts." *Boag v. MacDougall*, 454 U.S. 364, 368 (1982) (Rehnquist, J., dissenting).

The decision of the Court of Appeals in the present action does not conflict with any prior decisions of this Court or of the Courts of Appeals of any other circuit. Moreover, Petitioners' contention that the Court of Appeals misstated the applicable standard of review is simply not correct. The First Circuit's decision is essentially nothing more than an evaluation of the sufficiency of the evidence presented at trial, in relation to well established principles of Massachusetts law pertaining to claims of medical negligence and wrongful death. As Justice Taft stated in *Layne & Bowler Corp. v. Western Well Works, Inc.*, 261 U.S. 387 (1923),

> it is very important that we be consistent in not granting the writ of certiorari except in cases involving principles the settlement of which is of importance to the public as distinguished from that of the parties, and in cases where there is a real and embarrassing conflict of opinion and authority between the circuit courts of appeal.

Layne & Bowler Corp. v. Western Well Works, Inc., 261 U.S. 387, 393.

The Petitioners have referenced the language of Rule 10 in their Petition and appear to acknowledge that it poses a substantial obstacle to the review they seek from this Court. (Pet. Br. at 6). In an effort to overcome this obstacle, the Petitioners contend that the decision of the Court of Appeals created and applied a new standard for appellate review of a trial court's denial of a motion for judgment as a matter of

law. (Pet. Br. at 6-7). This contention is contrary to the clear language of the Court's decision. The Court of Appeals stated the appropriate standard of review in its decision when Judge Lynch wrote:

> We review de novo a district court's denial of a Rule 50 motion for judgment as a matter of law. But "our review is weighted toward preservation of the jury verdict," *Rodowicz*, 279 F.3d at 41, and "we must affirm unless the evidence was 'so strongly and overwhelmingly' inconsistent with the verdicts that no reasonable jury could have returned them," *Walton v. Nalco Chem. Co.*, 272 F.3d 13, 23 (1st Cir. 2001) (*quoting Negron v. Caleb Brett U.S.A., Inc.*, 212 F.3d 666, 668 (1st Cir. 2000).

Heinrich v. Sweet, 308 F.3d 48, 59-60 (1st Cir. 2002); (Pet. App. 14a).

The Petitioners claim that this statement by the Court of Appeals "is at odds with the teachings of this Court, the other circuits and the Commonwealth of Massachusetts." They go on to contend that by enunciating this standard, the Court of Appeals was then free to ignore the evidence presented at trial and to "substitute its own conclusions for those of the jury." (Pet. Br. at 7). MGH respectfully submits that the Petitioners' argument is an obvious mischaracterization of the decision by the Court of Appeals. The standard presented and followed by the Court of Appeals is well established and entirely in accordance with prior decisions of this Court and of the other circuits.

In *Walton v. Nalco Chemical Co.*, 272 F.3d 13 (1st Cir. 2001), the Court stated:

> Judgments entered as a matter of law are reviewed *de novo*, and will be affirmed "only if, after scrutinizing the proof and inferences derivable therefrom in the light most hospitable to [the plaintiff], we determine that a reasonable factfinder could have reached but one conclusion: that [the defendant] w[as] entitled to judgment."

Walton, 272 F.3d at 18. In fact, the Petitioners themselves acknowledged the propriety of this standard of review in their Consolidated Brief in Opposition to the briefs filed by the Respondents in the Court of Appeals, stating: "The district court may grant a motion for judgment notwithstanding the verdict only upon its determination that the evidence could lead a reasonable person to only one conclusion." *Plaintiffs-Appellees' Consolidated Brief in Opposition to Briefs of Defendants-Appellants William H. Sweet, M.D. and Massachusetts General Hospital*, at 4-5. The statement by the Court of Appeals, that it could only vacate the jury verdicts if the evidence was "so strongly and overwhelmingly inconsistent with the verdicts that no reasonable jury could have returned them," established perhaps the most stringent standard that an appellate court may apply when reviewing an issue on appeal. It is hardly a standard that would permit the Court of Appeals to ignore the evidence and substitute its own judgment for that of the jury, as the Petitioners suggest.

The Petitioners also contend that the Court of Appeals failed to consider all of the evidence presented at trial in the District Court, as required in accordance with this Court's

decision in *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133 (2000), ("in entertaining a motion for judgment as a matter of law, the court should review all of the evidence in the record."). *Reeves*, 530 U.S. at 150. MGH maintains that the Petitioners' argument in support of this assertion amounts to nothing more than conjecture and speculation. The language of the written decision by the Court of Appeals demonstrates a comprehensive, careful and detailed evaluation of all the evidence and a clear understanding by Judge Lynch of the numerous and complex factual, procedural, medical and technical aspects of the evidence and the proceedings in the Trial Court. One cornerstone of the decision by the Court of Appeals is its determination that "[t]here is *no evidence at all* in the record that BNCT hastened decedents' deaths." 308 F.3d at 61 (emphasis added). An example of the Court's careful consideration of the District Court record is its evaluation of the evidence relating to the question of whether BNCT hastened the deaths of Mrs. Sienkewicz or Mr. Heinrich. Despite the fact that the Plaintiffs only medical expert, Dr. Larry Junck admitted unequivocally during cross-examination that he could *not* state that the administration of BNCT hastened the deaths of either Mrs. Sienkewicz or Mr. Heinrich *in any way*,[3] the Court

---

3. When Dr. Junk was questioned as to whether BNCT hastened the deaths of either patient he testified:

> A. I think it would be very difficult for me to say what would have happened had they not received that treatment. That would be *just hypothetical* and is just the kind of thing that I would *have no basis for saying* what would have happened had they not received BNCT and perhaps received some other treatment.

(Cont'd)

of Appeals nevertheless undertook a detailed evaluation of the multiple, random references to various other aspects of the evidence identified by the Petitioners in their efforts to counter this apparently fatal admission by Dr. Junck. Throughout its opinion the Court of Appeals demonstrated that it clearly conducted a thorough examination of the issues raised by the Petitioners and the various evidentiary references offered by the Petitioners in support of their claims. The Court simply found that the evidence presented at trial was insufficient in certain crucial respects to establish the requisite elements of the Petitioners claims. The Petitioners were required to prove those elements, pursuant to well established principles of Massachusetts law, in order for the trial judge to permit their claims to be submitted to the jury. *See* 308 F.3d at 64-68; (Pet. App. 23a-30a).

(Cont'd)

Q. Or perhaps received no treatment whatsoever?

A. Perhaps.

****

Q. But you certainly *cannot say* that the administration of BNCT *in any way hastened* [Sienkewicz's] *death*, is that correct?

A. *That's correct.*

Q. And *you cannot say* that the administration of the BNCT *in any way hastened* George Heinrich's *death*, is that correct?

A. *That's correct.*

(JA 1116:10-20) (emphasis supplied).

B. The Court of Appeals properly vacated the jury verdicts against the Respondents, Massachusetts General Hospital and William H. Sweet, M.D., and ordered the entry of Judgment in their favor, based upon its determination that the evidence presented at trial was wholly inadequate and insufficient, as a matter of law, to support or uphold the original jury verdicts in favor of the Petitioners.

1. The Negligence Claims

As discussed previously, Dr. Larry Junck was the only expert presented by the plaintiffs at trial who was permitted to offer expert opinion testimony concerning the plaintiffs' negligence and wrongful death claims. However, Dr. Junck's testimony did not establish an appropriate basis for submission of the negligence and/or wrongful death claims to the jury, because Dr. Junck never stated that Dr. Sweet's treatment of either Mr. Heinrich or Ms. Sienkewicz deviated from the standard of care of the average qualified neurosurgeon practicing in 1960 and 1961. *Brune v. Belinkoff*, 354 Mass. 102, 109, 235 N.E.2d 793, 798 (1968); *Rogers v. Okin*, 478 F. Supp. 1342, 1384-85 (1979); *Stepakoff v. Kantar*, 393 Mass. 836, 840, 473 N.E.2d 1131, 1135 (1985). The *Brune* standard has remained the unaltered and well recognized criteria under Massachusetts law upon which the jury is to assess a physician's conduct and upon which the Court is to assess the sufficiency of a medical expert's testimony, in order to determine whether the claims warrant submission to the jury. Expert testimony is generally required in order for a plaintiff to meet the burden of proof established under *Brune*. As the Massachusetts Supreme Judicial Court stated in *Forlano v. Hughes*, 471 N.E.2d 1315 (Mass. 1984):

> It is only in exceptional cases that a jury instructed by common knowledge and experience may

> without the aid of expert medical opinion determine whether the conduct of a physician toward a patient is violative of the special duty which the law imposes as a consequence of this particular relationship.

Forlano v. Hughes, 471 N.E.2d 1315, 1319 (Mass. 1984).

Although Dr. Junck was not required to state his opinions in formulaic terms, tracking the exact language of the *Brune* decision, the plaintiffs *were* required to illicit at least some testimony from Dr. Junck focused upon the criteria presented in *Brune*. Dr. Junck's only testimony even approaching the *Brune* standard was his personal belief that the decision to proceed with BNCT, without knowing all of the potential risks to the patients, was "irresponsible" and "inappropriate." (JA 985:11-987:21) (see also JA 988:25-989:13). However, as noted by the Massachusetts Appeals court in *Broderick v. Gibbs*, 1 Mass. App. Ct. 822, 296 N.E.2d 708 (1973) (rescript opinion), testimony that amounts to nothing more than a difference of opinion concerning the advisability of a procedure, does not establish a departure from the standard of care. *Id.*, at 822. Since Dr. Junck's criticism of BNCT was not stated, either specifically or generally, in terms of the applicable standard of care under *Brune v. Belinkoff*, 354 Mass. 102, 109, 235 N.E.2d 793, 798 (1968), his opinions were insufficient as a matter of law.

Moreover, Dr. Junck's theory of liability was inconsistent with the jury's verdict in favor of the defendants on the plaintiffs' claims for lack of informed consent. MGH does not suggest that a jury verdict in favor of a physician as to informed consent would always be inconsistent with a negligence verdict against the physician. In the present case,

however, Dr. Junck's theory as to the *negligence* claims was premised exclusively upon the contention that the defendants should not have proceeded with the BNCT trials at all, due to the fact that they did not know, and indeed, could not know all of the risks, prior to initiating the treatment. The *informed consent* claims were similarly premised on the contention that the defendants failed to "disclose in a reasonable manner all significant medical information that the physician possesses . . . or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure." (JA 2601:10-16). The jury verdict in favor of the Respondents on the claims for lack of informed consent effectively established that Dr. Sweet was aware of all the information which a reasonable physician in his specialty should have possessed at that time and that he disclosed all such "significant medical information" to his patients. The criticism offered by Dr. Junck cannot logically or reasonably be deemed to establish the appropriate standard of care governing Dr. Sweet's conduct relative to a claim of medical negligence, because it would impose a finding of negligence upon every doctor providing any new treatment or medication, unless all of the risks of that treatment or medication were know. If Dr. Junck's theory of liability as to the Petitioners negligence claims were permitted to stand, then any doctor involved in clinical trials of a new type of treatment or a new medication, could be found negligent simply for proceeding with that new treatment or medication before it had developed to a point where all of the potential risks were known and could be disclosed to the patient. A doctor could not avoid liability on a subsequent claim of negligence even if that doctor informed the patient of all the known risks, explained that other potential risks were not yet known and explained that the full extent of those unknown

potential risks could only be determined by proceeding with the clinical trials. As a matter of public policy, such a standard could certainly have a chilling effect upon clinical trials of any new form of treatment or medication.

2. The Wrongful Death Claims

The Court of Appeals also ruled that the plaintiffs' claims for wrongful death should not have been presented to the jury, because the plaintiffs failed to offer any expert testimony to establish that the alleged acts or omissions of Dr. Sweet hastened the deaths of the decedents in any way. Although the plaintiffs' expert, Dr. Junck testified, over objection, that in his opinion the BNCT *caused* the deaths of Mrs. Sienkewicz and Mr. Heinrich, he also admitted that it was impossible to say whether the BNCT hastened the deaths of either Mrs. Sienkewicz or Mr. Heinrich, due to the fact that they would have died from their glioblastoma multiforme irrespective of whether they did or did not receive BNCT. (JA 945-946, 952-954, 1116 and 1129). The elements of compensable damages set out in the Massachusetts wrongful death statute permit a jury to award damages only for the *loss* of the decedent's care, comfort, guidance, support and other benefits resulting from the decedent's death. (JA 2610-2611). If the defendant's conduct did not hasten the death some way, the plaintiffs cannot be found to have lost any time with the decedent, during which the plaintiff could have enjoyed the benefits addressed under the statute. Under Massachusetts law, hastening of death must be established through expert testimony. *Edwards v. Warwick*, 317 Mass. 573, 577-578, 59 N.E.2d 194, 196 (1945). Without such expert testimony, any other evidence relied upon by the plaintiffs as constituting support for their wrongful death claims, must be considered insufficient as a matter of law.

Civatarese v. Gorney, 358 Mass. 652, 656, 266 N.E.2d 668, 671 (1971) (holding expert testimony necessary to establish causation in medical malpractice case).

During his pre-charge to the jury on September 10, 1999, and his final charge to the jury on October 8, 1999, Judge Young instructed the jurors that in order to establish their claims for wrongful death, the plaintiffs were required to demonstrate that the defendant's negligence shortened the lives of the decedents. (JA 2610-2611) This portion of the charge was in accordance with the case law of Massachusetts. *Walker v. Gage*, 223 Mass. 179, 182, 111 N.E. 766 (1916); *accord Corriveau v. United States*, 832 F. Supp. 19, 23 (D. Mass. 1993) (applying Massachusetts law); *Edwards v. Warwick*, 317 Mass. 573, 577-578, 59 N.E.2d 194, 196 (1945) and cases cited. Plaintiffs' counsel did not object to this portion of the charge. Although counsel for the Plaintiffs suggested to the Court that punitive damages could be awarded without the jury finding that BNCT hastened the deaths, he did not challenge the legal accuracy of the charge as to the plaintiffs' burden of proving hastening of the deaths. The Court did not revise any aspect of the charge based upon this suggestion by plaintiff's counsel. (JA 2619-2620).

In *Edwards v. Warwick*, the Supreme Judicial Court of Massachusetts held that "[r]ecovery may be had where there is substantial ground for a finding that the negligence has caused death to occur when it did, even though it would have occurred at no very remote date from other causes." *Edwards* 317 Mass. at 578, 59 N.E.2d 194, 196. In *Edwards*, there was testimony from a medical witness who treated the decedent before the accident and had seen her afterwards. He gave his opinion that her death was "hastened prematurely by the accident." *Edwards*, 317 Mass. at 577, 59 N.E.2d at 196. The Massachusetts Supreme Judicial Court ruled that:

> . . . in view of testimony of persons intimate with the deceased from which the jury could have found that there was a marked deterioration in her general health immediately following the accident . . . and in view of the definite opinion of the medical witness . . . we think that the jury could find that the accident had caused the death of the testatrix at an earlier date than that at which it would have come about from other causes. Such finding is not precluded by the fact that no witness attempted to testify by just how much death had been accelerated.

Edwards, 317 Mass. at 577-578, 59 N.E.2d at 196 (emphasis supplied).

Generalized references by Plaintiffs' counsel, during closing argument, to statistics regarding survival times for patients with glioblastoma multiforme, described in various journal articles that were never supported by expert testimony at trial as to their reliability or applicability to either Mrs. Sienkewicz or Mr. Heinrich, (JA 2675, 2691), are entirely insufficient to meet the plaintiffs' burden of proof as to hastening of death. (JA 945-946, 952-954, JA 1116 and 1129). The Court of Appeals correctly determined that the Plaintiffs did not present sufficient evidence at trial from any expert witness to establish that BNCT hastened the deaths of Mrs. Sienkewicz or Mr. Heinrich. Absent competent evidence of hastening of death, the plaintiffs' claims for wrongful death failed as a matter of law.

C. The Plaintiffs' Petition contains numerous misstatements of the evidence

MGH disputes the Petitioners' assessment of the accuracy and propriety of the decision by the Court of Appeals and submits that the accusatory language used by the Petitioners in criticizing the Court of Appeals is inappropriate. Statements made by the Petitioners relating to the evidence are equally inappropriate, with only minimal citation to specific pages of the Joint Appendix. The entire Petition contains only twenty such references to the Joint Appendix. Of the 6,693 pages contained in the Joint Appendix, the twenty references offered by the Petitioners pertain to only 36 pages of the record, 7 of which relate simply to a conference between counsel and the trial judge and the Court's instructions to the jury, rather than to actual testimony presented at trial. MGH recognizes that the Petitioners are not required to document all factual references with citations to the Joint Appendix. However, where their arguments are based upon issues of the sufficiency of the evidence, their failure to document the alleged evidence is indicative of the lack of such evidence. The Petitioners contend that there is "overwhelming evidence", (Pet. Br. at 21), to support their claims, without providing sufficient citation to those sections of the Joint Appendix where such overwhelming evidence might be found.

The most extreme example of the Petitioners' failure to provide supportive references is their repeated suggestion that the Defendants *knew*, prior to providing BNCT to Mrs. Sienkewicz and Mr. Heinrich, that it would cause them harm and would not provide any therapeutic benefits. At page 6 of the Petition, they state that the "Defendants' employees" testified that "they had *knowingly* violated the standard of

care in the interest of expediency." (Emphasis supplied). The Petitioners have offered no actual quotations of this supposed testimony or any references to the Joint Appendix to support this assertion. MGH submits that the statement is not accurate. On pages 8 and 9 of the Petition, the Petitioners state that the Defendants "understood" that retained boron in the cell walls of healthy blood vessels would cause damage to those vessels, but that the defendants "decided to forge ahead, in the interest of saving time". Again, the Petitioners fail to provide any references on pages 8 or 9 of the Petition to actual evidence that might support this contention. The Petitioners' assertion is incorrect. In fact, the evidence presented at trial, particularly a medical article, (the Asbury article), published in 1972 and introduced by the Plaintiffs as Exhibit 1 at trial, demonstrated that Dr. Sweet did not become aware of complications associated with retained boron in the cell walls of the blood vessels until *after* the conclusion of the BNCT clinical trials at MIT. Moreover, this problem was only identified as a result of the autopsy findings of the patients who had participated in those trials. (JA 2828-2853).

The decision of the Court of Appeals also noted that, "some of Dr. Junck's opinions rested on particular data or publications that do not support his conclusions and *have been mischaracterized by plaintiffs in their briefs to us*." (Pet. App. at 24a-25a). (Emphasis supplied).

A final example of a mis-statement of the evidence in the Petition is the assertion made in footnote 14, on page 22 of the Petition, where the Petitioners assert:

> The Panel ignores *all of the Plaintiffs' evidence* that (Mrs. Sienkewicz's) earlier craniotomy had left her *without tumor* at the time of the BNCT

(Emphasis supplied). Footnote 14 does not contain any reference to the pages of the Joint Appendix that contain "*all of*" this evidence relied upon by the Petitioners. Counsel for the Plaintiffs first attempted to raise this argument, unsuccessfully, near the end of trial, during cross-examination of Gregory Koski, M.D., an MGH witness. (JA 2159-2163). However, during the pre-charge conference, the Court instructed plaintiffs' counsel that he was not permitted to argue in his closing that Mrs. Sienkewicz did not have glioblastoma multiforme when she received BNCT, because there was no evidence to support that suggestion. (JA 2345 and 2553-2554).

CONCLUSION

The arguments presented by the Petitioners concerning the decision of the Court of Appeals in this case do not warrant further appellate review by this Court. The Petitioners have not raised any legitimate "questions of wide import under the Constitution, laws, (or) treaties of the United States", *Boag v. MacDougall*, 454 U.S. 364, 368 (1982) (Rehnquist, J., dissenting). No aspect of the decision of the Court of Appeals involves a conflict of opinion on a federal question among any of the lower federal courts. In fact, the decision does not involve any issues of *federal law*. The only claims presented to the jury at trial in this matter were *state law* claims, for alleged negligence, alleged wrongful death and an alleged failure to obtain informed consent. The case was decided upon principles that are well settled under the laws of the Commonwealth of Massachusetts and do not require consideration by this Court.

The decision of the Court of Appeals was simply an evaluation and assessment of the sufficiency of the evidence presented at trial, with reference to specific elements that the Plaintiffs were required to prove in order to warrant submission of their claims to the jury. The errors asserted by the Petition relate to factual issues and the application of properly stated principles of Massachusetts law to those factual issues. Consequently, the Petitioners' arguments fall squarely within the language of Rule 10 of this Court, which states: "[A] petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law."

MGH submits that the review requested by the Petitioners would require a complete re-evaluation by this Court of the same evidence within the Joint Appendix evaluated by the Court of Appeals. The Petitioners have provided limited and insufficient citations in their Petition to the actual evidence in the Joint Appendix. The decision of the Court of Appeals demonstrates clearly that it performed a careful, detailed and complete review of that evidence and applied the correct rules of law under the correct standards of review. MGH requests that this Court deny the Petition.

Respectfully submitted,

JOSEPH L. DOHERTY, JR.
Counsel of Record
JOSEPH L. DOHERTY, JR.
AND ASSOCIATES
Attorneys for Respondent
Massachusetts General Hospital
225 Franklin Street
26th Floor
Boston, MA 02110
(617) 217-2837